

**RESULTS OF INVESTIGATION:** The article was shipped in bulk, and after its receipt by D & L Slade Co., it was repacked into the containers described above.

**LIBELED:** 1-25-57, Dist. Mass.

**CHARGE:** 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use since no indications for use or dosage directions were given; and 502 (f) (2)—the article was essentially a laxative, and its labeling failed to warn that frequent or continued use may result in dependence on laxatives to move the bowels; and the labeling failed also to warn that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present.

**DISPOSITION:** 2-19-57. Consent—claimed by D & L Slade Co. and relabeled.

### **DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS**

**5229. Digitalis tablets.** (F. D. C. No. 39683. S. No. 47-311 M.)

**QUANTITY:** 11 1,000-tablet btls. at Reading, Pa.

**SHIPPED:** 8-2-56, from St. Louis, Mo., by Keith-Victor Pharmacal Co.

**LABEL IN PART:** (Btl.) "Enteric coated green 1,000 tablets Digitalis U. S. P. \* \* \* 1½ grains."

**RESULTS OF INVESTIGATION:** The article was shipped in a bulk container labeled, in part, "Digitalis 1½ gr. Tablets Each Tablet contains Digitalis . . . 1½ gr.," and was repackaged and relabeled as above by the consignee.

Analysis showed that the digitalis potency of the article fell below its professed potency of 1½ grains of U. S. P. digitalis per tablet.

**LIBELED:** 11-9-56, E. Dist. Pa.

**CHARGE:** 501 (b)—the article purported to be and was represented as "Digitalis Tablets," a drug the name of which is recognized in the United States Pharmacopeia; and, when shipped and while held for sale, its strength differed from the standard set forth in such compendium; and 502 (a)—the label statement "Digitalis \* \* \* 1½ grains" was false and misleading.

**DISPOSITION:** 2-7-57. Default—destruction.

**5230. Nasal spray.** (F. D. C. No. 39486. S. No. 52-694 M.)

**QUANTITY:** 828 btls. at Newark, N. J.

**SHIPPED:** 8-16-56, from Brooklyn, N. Y., by Success Chemical Co., Inc.

**LABEL IN PART:** (Btl.) "20 cc R/W Tyro-Hist Nasal Spray."

**LIBELED:** 9-25-56, Dist. N. J.

**CHARGE:** 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 0.02 percent of tyrothricin; and 502 (a)—the label statement "Contains in Aqueous Isotonic Solution: Tyrothricin . . . 0.02%" was false and misleading as applied to the article, which contained less than 0.02 percent of tyrothricin.

**DISPOSITION:** 11-14-56. Default—destruction.

**5231. Halazone tablets.** (F. D. C. No. 39708. S. Nos. 28-250 M, 28-298 M.)

**QUANTITY:** 400 cases, each containing 3 ctns. of 100 btls. each, at Oakland, Calif.

**SHIPPED:** On an unknown date, from Chicago, Ill.

**LABEL IN PART:** (Btl.) "100 Water Purification Tablets FOR PURIFYING DRINKING WATER IN CANTEENS HALAZONE N. N. R. \* \* \* Each tablet contains 0.004 Gm. ( $\frac{1}{16}$  grain) of Halazone with sodium carbonate, sodium chloride and boric acid."

**LIBELED:** 11-30-56, N. Dist. Calif.

**CHARGE:** 501 (b)—the article purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium; and its strength, while held for sale, differed from the standard set forth in such compendium.

**DISPOSITION:** 12-11-56. Default—destruction.

**5232. Halazone tablets.** (F. D. C. No. 39672. S. No. 37-306 M.)

**QUANTITY:** 188 cases, 300 btls. each, at Brooklyn, N. Y.

**SHIPPED:** 8-23-55, from Topeka, Kans.

**LABEL IN PART:** (Btl.) "Tablets Water Purification Individual (Halazone) 100 Tablets \* \* \* Each tablet contains: P-Sulfonedichloramido Benzoic Acid ( $\frac{1}{16}$  Grain) Sodium Carbonate Sodium Chloride Boric Acid" or "100 Water Purification Tablets For Purifying Drinking Water in Canteens \* \* \* Halazone N. N. R. (P-sulfonedichloramido-benzoic acid) Each tablet contains 0.004 Gm. ( $\frac{1}{16}$  grain) of Halazone with sodium borate and chloride."

**RESULTS OF INVESTIGATION:** Analysis showed that the tablets contained from 44 percent to 91 percent of the declared amount of halazone. The National Formulary provides that *halazone tablets* contain not less than 90 percent of the labeled amount of halazone.

**LIBELED:** 11-9-56, E. Dist. N. Y.

**CHARGE:** 501 (b)—the article purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength, while held for sale, differed from the standard set forth in such compendium.

**DISPOSITION:** 1-11-57. Default—destruction.

**5233. Plastic adhesive strips.** (F. D. C. No. 39671. S. No. 44-918 M.)

**QUANTITY:** 60 12-pkg. ctns. at Washington, D. C.

**SHIPPED:** 9-4-56, from New Rochelle, N. Y., by C. I. Lee & Co., Inc.

**LABEL IN PART:** (Pkg.) "10 $\frac{3}{4}$  x 3 New Plastic Adhesive Strips Washable Waterproof Individually Wrapped Sterilized."

**RESULTS OF INVESTIGATION:** Examination showed that the article was not sterile but was contaminated with viable micro-organisms.

**LIBELED:** 11-5-56, Dist. Columbia.

**CHARGE:** 501 (b)—the article purported to be and was represented as a drug, "Adhesive Absorbent Bandage," the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when shipped, its quality and purity fell below the standard set forth in such compendium.

**DISPOSITION:** 12-5-56. Default—destruction.

**5234. Clinical thermometers.** (F. D. C. No. 39450. S. Nos. 48-862/3 M.)

**QUANTITY:** 28 doz. *oral thermometers* and 19 doz. *rectal thermometers* at Milwaukee, Wis.